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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,876	03/15/2004	Sharen A. Godwin	5714-001	1938

25184 7590 07/12/2010

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EXAMINER	
PASS, NATALIE	

ART UNIT	PAPER NUMBER
3686	

MAIL DATE	DELIVERY MODE
07/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,876	GODWIN ET AL.	
	Examiner	Art Unit	
	Natalie A. Pass	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4 February 2010 has been entered.

2. This communication is in response to the Request for Continued Examination and amendment filed on 4 February 2010. Claims 1, 8, and 16 have been amended. Claims 2-4 have been previously cancelled. Grounds of rejection for claims 1, 5-20 are presented in the instant application as set forth in detail below.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1, 5-20 are rejected under 35 U.S.C. §101 for substantially the same reasons given in the previous Office Action (paper 20090930). Further reasons appear hereinbelow.

A) Claims 1, 8, and 16 have been amended to recite "a 'computer readable data source" in lines 3, respectively. As per claims 1, 5-20, these appear to be directed toward a method or process of identifying prospective clinical trial participants. Based on Supreme Court

precedent, and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr,* 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson,* 409 U.S. 63, 70 (1972); *Cochrane v. Deener,* 94 U.S. 780,787-88 (1876).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

In the instant application, Appellant's method steps continue to fail the first prong of the new Federal Circuit decision since they are not required to be tied to another statutory class and can be performed without the use of a particular apparatus. In particular, Applicant's claims do not recite who or what is performing the method steps. Moreover, Examiner respectfully submits that a "computer readable data source" does not require the use of a machine or apparatus, as "computer readable data source" does not exclude papers that can be scanned or are "readable" by a computer scanner.

Furthermore, the method steps fail to unambiguously require transformation of underlying subject matter to a different state or thing. The mere manipulation and production of

non-functional descriptive material (i.e., "patient identifiers") is not a transformation because a patient identifier is not statutory subject matter.

Dependent claims 5-7, 9-15, 17-20 merely add further details of the methods recited in claims 1, 8, and 16 without including any tie to another statutory category or any transformation of subject matter into a different state or thing. Thus, claims 1, 5-20 are non-statutory since they are not requisitely tied to another statutory class and they do not requisitely transform underlying subject matter to a different state or thing.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Newly added claims 1, 5-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) Claims 1, 8, and 16 recite limitations that are new matter, and are therefore rejected. The added material which is not supported by the original disclosure is as follows:

- a "computer readable" data source, as disclosed in claims 1, 8, and 16 at lines 3, respectively.

35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. "New matter" constitutes any material which meets the following criteria:

a) It is added to the disclosure (either the specification, the claims, or the drawings) after the filing date of the application, and

b) It contains new information which is neither included nor implied in the original version of the disclosure. This includes the addition of physical properties, new uses, etc.

In particular, the Examiner was unable able to find any support for this newly added language within the specification as originally filed on 15 March 2004. Applicant is respectfully requested to clarify the above issues and to specifically point out support for the newly added limitations in the originally filed specification and claims.

(B) Claims 5-7, 9-15, 17-20 incorporate the features of independent claims 1, 8, and 16, through dependency, and are also rejected.

Applicant is required to cancel the new matter in the reply to this Office Action.

7. If Applicant continues to prosecute the application, revision of the specification and claims to present the application in proper form is required. While an application can, be amended to make it clearly understandable, no subject matter can be added that was not disclosed in the application as originally filed on 15 March 2004.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

NOTE: The following rejections assume that the subject matter added in the 4 February 2010 amendment are NOT new matter, and are provided hereinbelow for Applicant's consideration, on the condition that Applicant properly traverses the new matter objections and rejections made in sections 6-7 above in the next communication sent in response to the present Office Action.

9. Claims 1, 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al., U.S. Patent Application Publication Number 2003/0046114, for substantially the same reasons given in the previous Office Action (paper 20090930), and further in view of Blake et al., U.S. Patent Application Publication Number 20050071189. Further reasons appear hereinbelow.

(A) As per claim 1, Davies teaches a method used by a research management organization to acquire information relating to potential clinical trial participants meeting predetermined criteria using a computer readable data source that includes the dictation records of at least one healthcare professional containing information relating to the medical conditions

of a plurality of patients identified by non-personal identifiers, said data source being in the form of a data stream generated during transcription of dictated records comprising:

a) inputting a search criteria based on participant criteria into the data source to select the records of patients that potentially meet said criteria, the patients being identified by non-personal identifiers (Davies; Abstract, paragraphs [0013]-[0015], [0018], [0023]-[0026], [0032], [0063]-[0065], [0086]); and

b) transmitting said non-personal patient identifiers to said healthcare professional to enable said healthcare professional to contact said patients regarding said clinical trial (Davies; paragraphs [0032], [0053]- [0055], [0086]).

Davies fails to explicitly disclose

receiving from said healthcare professional the names of patients who have expressed an interest in participating in said clinical trial.

However, the above features are well-known in the art, as evidenced by Blake.

In particular, Blake teaches

receiving from said healthcare professional the names of patients who have expressed an interest in participating in said clinical trial (Blake; paragraphs [0007]-[0009], [0021]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Davies to include these limitations, as taught by Blake, with the motivations of "increas[ing] the pool size and the success rate of patient recruitment for clinical trials" by "motivating and involving physicians in the recruitment of their patients" (Blake; paragraphs [0006], [0009]).

(B) As per claims 5-7, Davies and Blake teach a method as analyzed and discussed in claim 1 above

wherein said healthcare professional is selected from the group consisting of physicians, dentists, chiropractors, hospitals and clinics (Davies; paragraph [0053]);

wherein said predetermined criteria include at least one criterion selected from the group consisting of disease state, ICD code, and patient complaint (Davies; paragraphs [0011], [0018], [0032]); and

wherein said data source includes at least one additional source of information relating to the medical conditions of said patients selected from the group consisting of billing records, laboratory records, and admission records, and demographic information (Davies; paragraphs [0023]-[0025], [0052]).

(C) As per claim 8, Davies and Blake teach a method used by a research management organization to identify prospective clinical trial participants meeting predetermined criteria using a computer readable data source including the dictation records of at least one healthcare professional containing information relating to the medical conditions of a plurality of patients identified by non-personal identifiers comprising:

a) receiving predetermined criteria from a clinical researcher (Davies; Abstract, paragraphs [0013]-[0015], [0063]);

b) preparing and inputting a search query based on said predetermined criteria (Davies; Abstract, paragraphs [0013]-[0015], [0063]);

c) selecting non-personal identifiers of patients in said data source that potentially meet said criteria (Davies; paragraph [0086]); and

d) transmitting said identifiers to said healthcare professional to enable said healthcare professional to contact patients who would want to consider participating in said trial (Davies; paragraphs [0032], [0053]- [0055]).

Davies fails to explicitly disclose

receiving from said healthcare professional the names of patients who have expressed an interest in participating in said clinical trial.

However, the above features are well-known in the art, as evidenced by Blake.

In particular, Blake teaches

receiving from said healthcare professional the names of patients who have expressed an interest in participating in said clinical trial (Blake; paragraphs [0007]-[0009], [0021]).

The motivations for combining the respective teachings of Davies and Blake are as given in the rejection of claim 1 above, and incorporated herein.

(D) As per claims 9-15, Davies and Blake teach a method as analyzed and discussed in claim 8 above

wherein said data source is a data stream generated during transcription of dictated records (Davies; paragraph [0098]);

wherein said non-personal identifier is "an alphanumeric identifier (Blake; paragraph [0025]);

wherein said dictation records are transcribed dictation records (Davies; paragraphs [0022]-[0025], [0053]-[0054], [0098]);

wherein said healthcare professional is selected from the group consisting of physicians, dentists, chiropractors, hospitals and clinics (Davies; paragraph [0053]);

wherein said predetermined criteria include at least one criterion selected from the group consisting of disease state, ICD-9 code and patient complaint (Davies; paragraphs [0011], [0018], [0032]);

wherein said data source includes at least one additional source of information relating to the medical conditions of said patients selected from the group consisting of billing records, laboratory records, and admission records (Davies; paragraphs [0023]-[0025], [0052]); and

wherein said data source includes the geographical locations of said patients (Davies; paragraph [0015]).

The motivations for combining the respective teachings of Davies and Blake are as given in the rejection of claim 1 above, and incorporated herein.

(E) As per claim 16, Davies and Blake teach a method used by a research management organization to identify prospective participants for a clinical trial who meet participant criteria from a computer readable data stream of individual patient records created during transcription of the dictation of at least one healthcare professional containing information relating to the medical conditions of a plurality of patients identified by non-personal identifiers comprising:

a) preparing a search query based on said predetermined criteria (Davies; Abstract, paragraphs [0013]-[0015], [0063]);

b) comparing each of said records against said query immediately following creation of the record (Davies; paragraphs [0024], [0032], [0053]-[0054], [0069]);

c) selecting non-personal identifiers of patients in said data stream having records that potentially meet said criteria (Davies; paragraphs [0018], [0023]- [0024], [0032], [0064]-[0065], [0086], [0098]); and

d) transmitting said non-personal identifiers of selected patients to said healthcare professional for use by the healthcare professional in obtaining contact authorization from selected patients (Davies; paragraphs [0053]- [0055], [0086]).

Davies fails to explicitly disclose

e) receiving the names of patients who have consented to be interview regarding the clinical trial from said healthcare professional; and

f) contacting patients whose names are received from said healthcare professional.

However, the above features are well-known in the art, as evidenced by Blake.

In particular, Blake teaches

e) receiving the names of patients who have consented to be interview regarding the clinical trial from said healthcare professional (Blake; paragraphs [0007]-[0009], [0021], [0036]-[0038]); and

f) contacting patients whose names are received from said healthcare professional (Blake; paragraphs [0007]-[0009], [0021], [0036]-[0038]).

The motivations for combining the respective teachings of Davies and Blake are as given in the rejection of claim 1 above, and incorporated herein.

(F) As per claims 17- 20, Davies and Blake teach a method as analyzed and discussed in claim 16 above

wherein said query is based on information provided by a clinical researcher (Davies; Abstract, paragraphs [0013]-[0015], [0063]), said method further including the step of providing the identification of authorizing patients to said researcher (Davies; paragraphs [0032], [0053]-[0055], [0063], [0092]);

wherein said data stream includes the geographical location of said patients (Davies; paragraph [0015], [0023]-[0024], [0098]);

wherein said data stream includes dictation records of a plurality of "users" (reads on "healthcare professionals") (Davies; paragraphs [0025], [0065]), the identifier of each selected patient being transmitted to the healthcare professional originating the record relating to the medical conditions of the selected patient (Davies; paragraphs [0032], [0053]- [0055]); and

wherein said data stream is accessed after transcription (Davies; paragraphs [0023]-[0024], [0032], [0053]-[0054], [0069], [0086], [0098]).

The motivations for combining the respective teachings of Davies and Blake are as given in the rejection of claim 1 above, and incorporated herein.

Response to Arguments

10. Applicant's arguments filed 4 February 2010 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 4 February 2010.

(A) At page 7 of the 4 February 2010 response, Applicant argues the rejection of method claims 1, 5-20 under 35 U.S.C. § 101. These arguments are not persuasive. As discussed above regarding Applicant's newly added limitations of a "computer readable data source," Examiner respectfully submits that a "computer readable data source" does not require the use of a machine or apparatus, as a "computer readable data source" can include a paper that can be scanned or is "readable" by a computer scanner, and moreover, Examiner submits that there is neither machine nor transformation, as analyzed in the Federal Circuit decision, and as discussed in the 2010 Supreme Court analysis of *Bilski v. Kappos*, present in the claims.

(B) The remainder of Applicant's arguments filed 4 February 2010 have been fully considered but they are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied references Bruschi et al., U.S. Patent Application Publication Number 2004/0172293, Toto, U.S. Patent Application Publication 20040078216, Kahn et al., U.S. Patent Application Publication Number 20030065669, Gotlib et al., U.S. Patent

Application Publication Number 20040152952, Schoenberg, U.S. Patent Application Publication Number 20070150372, and Schoenberg U.S. Patent Application Publication Number 20090089098, teach the environment of identifying clinical trial participants.

12. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington D.C. 20231

or faxed to: **(571) 273-8300**.

For informal or draft communications, please label "PROPOSED" or "DRAFT" on the front page of the communication and do NOT sign the communication.

After Final communications should be labeled "Box AF."

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/N. A. P./
Examiner, Art Unit 3686
July 7, 2010

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686